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Costco Food Safety & Quality Audit

Company Information	Audit Information
Facility: T3836 - ROSS PRODUCTS - ABBOTT LABORATORIES Address: 1250 W MARICOPA HWY CASA GRANDE, ARIZONA UNITED STATES , 85222 Contact: MS. SHARON BOTTOCK Title: Phone: 520-421-6600 Fax: Email:	Audit#-Visit#: 78119 - 64242 Audit Type: BASE1CO-Costco Food Safety & Quality Audit Template Version: 1.3 Audit Categoty: REGULAR Auditor: RICHARD COVINGTON Auditor Phone: 570-523-2042 Audit Start Time: 09-APR-2007 08:00:00 AM Audit End Time: 09-APR-2007 05:00:00 PM
: Victor Yubeta : Sharon Bottock : Victor Yubeta	

Section 2 Facility and Operating Profile

No	Question/Notes	Answer
1	Facility and Operations Description: Ross Products is a division of Abbott Laboratories. The division has 5 manufacturing locations and is headquartered in Columbus, Ohio. The Casa Grande facility is about 600,000 square feet on a 240 acre lot on the west side of town. It was built in 1985. There are 4 production lines and all products are shelf stable and of a medical nutritional nature. 450 personnel are employed at this location and production operates 24 hours a day, 7 days a week with sanitation performed by in-house personnel as scheduled.	See Note
2	Regulatory Inspection Type: Regulatory Inspections include: FDA; State and County	FDA
3	Products made at this facility: Powdered and liquid infant formula's.	See Note
4	Products made for the client: Kirkland 3/ 51,4 oz units/ case of powdered infant formula; sealed in a composit can with metal ends. The top end is a metal easy open end.	See Note
5	Did the facility provide proof of Homeland Security registration? XXXXXXX7260	Yes
6	What is the average lot size in pounds (coded and identifiable)?	210,000 lbs
7	What is the most probable cause of accidental product contamination? Extraneous product material (small black specs of scorched material–very infrequent) and Consumer, even though the container has a replacement lid to be utilized after the original seal is broken and the metal lid removed.	Extraneous material
8	The following departments and individuals participated in the audit process: Compliance Officer, Victor Yubeta; Sr Document Coordinator, Karen McKay; Plant Manager, Roger Hill; Operations Manager, Jeffrey Starling; Several supervisors on the production floor.	See Note

Section notes:

Status : Excellent

- Corrective Action Requirements: Please email a corrective action response addressing all deficiencies listed in this report to Costco Wholesale and NSF-Cook & Thurber within 10 working days of receiving this report. C/ O Steve Bell (sdbell@costco.com); Milinda Dwyer (mdwyer@costco.com); Mike Freal (mfreal@costco.com);

11-cv-4017MWBT
1012A

Jennifer Fitzpatrick (fitzpatrick@nsf.org)

- Re-audit Requirements: In the event your facility requires a reaudit, which is defined as an audit score below 85 or an item scored as a critical finding/ automatic failure, please contact an audit company representative and arrange for an appointment date within 45 days of your original audit date. If a reaudit date is not possible within 45 days contact a Costco representative.

Score Summary By Section	
Section Name	Section Score
Section A Administration and Regulatory Compliance	96.00%
Section B HACCP Management	95.00%
Section C Facilities and Equipment	97.00%
Section D Sanitation, Housekeeping and Hygiene	95.00%
Section E Rodent and Pest Control Management	95.00%
Section F Receiving and Inventory Control	95.00%
Section G Process and Product Evaluation	95.00%
Section H Packaging and Labeling	97.00%
Section I Storage and Shipping	95.00%
Section J Analytical Records and Laboratory Support	96.00%
Section K Food Defense	97.00%
Food Safety, Quality and Food Defense Audit Score:	95.73%

Category Scoring Guide

95-100 = Excellent
90-94.99 = Good
85-89.99 = Fair
80-84.99 = Needs Improvement -- Requires Re-Audit
<80 or Critical in any Element = Unacceptable -- Requires Re-Audit

Automatic Audit Failures

- Direct Product Contamination
- Adulterated or Misbranded product
- Facility was not operating in sanitary condition
- HACCP System Failure - Plant was producing product that did not meet critical limit(s); appropriate corrective action was not taken; or no HACCP Plan.
- Critical Deficiency in any one category

Section 1 Additional Audit Information

No	Question/Notes	Answer
1	Costco Audit ID	78119
2	Previous Audit Date	4/10/06
3	Previous Audit Score	92%
4	Audit Start Time	7:45 am
5	Audit End Time	5:00 pm
Section notes:		

Section A Administration and Regulatory Compliance

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Section A Administration and Regulatory Compliance

No	Question/Notes	Answer
1	**Food Safety, Quality and Food Defense Organization and Responsibilities** A plant organizational chart identifie s the reporting structure of the plant maA plant management organization changed the Quality Manager. The chart is 2007 current, dated and signed and the Quality Managers responsibilities are clearly documented and include the release of withheld and retained products.Quality has 14 reports at the plant level including: Chemistry lab, Quality, Micro, Compliance, Quality Engineering,and CAPA Coordinator. A plant management organization chart identifies the reporting structure of the plant management and the Quality Manager. The chart is current, dated and signed and the Quality Managers responsibilities are clearly documented and include the release of withheld and retained products.	Acceptable
2	**Food Safety, Quality and Food Defense Policies and Procedures** Detailed policies and procedures that address relevant food safety, quality and security requirements for the receiving, handling, manufacturing and shipping of product are well organized and available. Testing procedures, sampling programs and accept/ reject criteria are defined.Raw material testing and packaging acceptance plans are detailed and conducted on each lot received. Detailed policies and procedures that address relevant food safety, quality and security requirements for the receiving, handling, manufacturing and shipping of product are well organized and available. Testing procedures, sampling programs and accept/ reject criteria are defined. -	Acceptable
3	**Specific Training Goals and Programs for Management and Operating Personnel** Training documentation demonstrates a commitment by management and includes training of all new employees in GMPs and basic food handling sanitation. Refresher training is provided on a regular basis, is documented on an individual basis and includes testing to document understanding. Supervisors and above must attend an academy training program at the divisional training location.	Excellent
4	**Recall Plan and Procedures** A documented plant specific Recall Plan is available that clearly defines a recall coordinator, identifies the recall team members and describes their responsibilities. Office and after-hour telephone contact numbers of all recall team members is available for all team members. The Recall Plan is reassessed and signed at least annually. A documented plant specific Recall Plan is available that clearly defines a recall coordinator, identifies the recall team members and describes their responsibilities. Office and after-hour telephone contact numbers of all recall team members is available for all team members. The Recall Plan is reassessed and signed at least annually.	Acceptable
5	**Regulatory Compliance** A file of regulatory visits and reports is maintained and includes third party audits and audits conducted by customers. An FDA inspection was conducted on 12/ 11-14/ 06; no issuance of FDA 483 was made.	Acceptable
6	**Document and Records Management** A document control policy is in place that identifies current revision status, specifies time limit for holding of files and indicates proper disposition of outdated documents and records. Records are indexed and easily retrievable. All formulation are controlled through the Corporate Offices. Only plant-specific procedures can be modified locally.	Excellent
7	**Change Management** A policy describing how the facility manages and communicates changes in specifications, policies and procedures in order to maintain continuity and the control of systems is documented. Any department can initiate a change request if appropriate procedures are defined, with approvals.	Acceptable
8	**Documentation to Track Effectiveness of Policies** Documented management reviews are conducted at least annually to evaluate the level of conformance to operational policies and assure that policies are properly managed, current and appropriate.	Acceptable
9	**Management Awareness and Commitment to Food Safety, Quality & Food Defense** Management is committed to food safety and quality and actively supports it through training programs, auditing for compliance to policies and provision of corrective actions. The plant is exceptionally well equipped and maintained.	Acceptable

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Section A Administration and Regulatory Compliance

No	Question/Notes	Answer
10	Crisis and Natural Disaster Management A crisis management plan is in place that defines emergency procedures, outlines the crisis team members and provides key contacts with 24/7 access. Team members have received specific training in crisis management and team meetings are documented.	Excellent
11	Customer/Consumer Complaints (Policies, Follow Up and Response) A written customer complaint program that addresses responsibilities, response time and corrective actions based on the investigation of a complaint is in effect. All complaints are handled at the Division headquarters and appropriate information and summaries are reported to the plant.	Acceptable
Section notes:		

Section B HACCP Management

No	Question/Notes	Answer
1	Prerequisite Programs Ten Prerequisite programs are well developed, documented and monitored. All sanitation and maintenance related programs are highly developed.	Acceptable
2	Preliminary HACCP Tasks A HACCP team is assembled and team member responsibilities are clearly identified. The team has constructed flow diagrams outlining each step in the process and has performed an on site review to verify its accuracy.	Acceptable
3	Hazard Analysis (HACCP Principle 1) The HACCP team has prepared a list of all chemical, physical and biological hazards that may occur and has conducted a hazard analysis to identify the hazards that are critical and controllable.	Acceptable
4	Critical Control Points (HACCP Principle 2) Documentation for determining a step or process as a CCP or not, is clearly and thoroughly explained and is scientific based. Meetings are conducted on a regular basis by the HACCP team to review any changes in the process that might affect the CCP determination. The Scientific basis for CCP's is from data in the Infant Formula Act.	Acceptable
5	Critical Limits (HACCP Principle 3) Control measures identifying operating and critical limits that are measurable, have been established and validated for each CCP; based on the Infant Formula Act Data.Limits are defined and include potentially toxic levels of some ingredients.. Process capabilities are documented to establish that CCP limits are compatible with the plant process and that limits are attainable.	Acceptable
6	CCP Monitoring (HACCP Principle 4) CCP monitoring procedures are conducted at a frequency sufficient enough to detect any loss of control. Data is evaluated by those empowered to implement corrective actions and is documented on clearly identified HACCP records. A deviation log is kept and records are signed.	Acceptable
7	Corrective Actions (HACCP Principle 5) Corrective actions are developed for each CCP and include instructions with the necessary actions to take to secure product and bring the CCP under control in the event a critical limit is exceeded. Continuous monitoring/ recording flow charts have been added to the processing system, to provide monitoring that complies with the documented plan.	Acceptable
8	Verification and Validation (HACCP Principle 6) Documentation is available confirming the HACCP plan is scientifically and technically sound and that all hazards have been identified and CCPs are effective and valid. Validation of the plan is performed and documented on an annual basis.	Acceptable
9	Documentation and Record Keeping (HACCP Principle 7) HACCP procedures are documented with detailed corrective actions and product dispositions. Final records are in ink, signed by the operator, supervisor and HACCP reviewer and without missing data or blanks. Records are securely stored and easily retrievable. Required compliance documentation is well organized and readily available. Records are on appropriate forms and entries are legible and signed.	Acceptable
Section notes:		

Section C Facilities and Equipment

No	Question/Notes	Answer
1	**Potable Water, Ice, Backflow Prevention, Steam and Waste Water Management** All water supply is potable, is supplied by the Arizona Water Company from a wll dedicated specifically to the plant,meets local requirements and is tested at least annually. Water lines and hose drops are fitted with backflow prevention devices that are tested by a trained inspector at least annually. There are no dead ends on potable water lines and no hose nozzles were observed submerged in water reservoirs or left laying on the floor. An adequate supply of hot and cold water is readily available for production, sanitation and handwashing. There is a documented procedure for handling backed up drains in production and no sewage disposal problems were observed.	Acceptable
2	**Plant Construction and Design** The facility is constructed in a manner conducive to handling product in a sanitary manner. Most of the building exterior is block and concrete while the interior is tile and sanitary glass board.No observations of overhead contamination or cross contamination were observed. Materials are easily cleanable, floors are well drained and drains have traps and covers. No objectionable odors, fumes or vapors were present. Interior air supplies are screened and filtered and no dust or standing water was observed around the exterior. An essential glass and brittle plastic program is monitored monthly. The grounds surrounding the building are very clean, well landscaped and provided with well designed drainage and run off holding basins.	Excellent
3	**Plant Condition (Walls, Ceilings, Floors, etc.)** Walls, ceilings and floors are well maintained, orderly, clean and sealed. No evidence of water leakage, rust or flaking paint was observed. No string, rope, wire or tape was being used as supports or temporary repairs. Overhead structures were clean and free of buildup.	Excellent
4	**Ready To Eat (RTE) Operational Areas**	N/A
5	**Employee Support Facilities** The cafeteria, locker room and toilet facilities are adequately sized, physically separated from food production areas and are maintained in a sanitary condition. Toilet facilities are mechanically ventilated to the outside and doors are self-closing and do not open directly into the production areas. Signs are clearly posted in locker rooms, toilet facilities and at entrances to work areas reminding employees to wash and sanitize their hands before starting work and when leaving toilet facilities.	Acceptable
6	**Handwashing Facilities** Sanitation facilities are well posted throughtout the facility. Hand washing facilities are provided in locker rooms, toilet facilities and at entrances to work areas. They are adequate in size, quickly deliver tempered water and are maintained with hand soap, hand sanitizer and single service towels. Hands-free activated faucets are available in and adjacent to processing areas.	Acceptable
7	**Equipment Layout, Design and Conditions** Nearly all equipment is made from Stainless Steel. Equipment is designed, installed and maintained in a manner that provides a safe, wholesome and quality product with easy access for cleaning and sanitizing. Where equipment may make direct product contact, it is constructed with materials that are smooth, impervious, non-toxic, non-absorbent and corrosion resistant with appropriate covers and no metal-to-metal contact between moving parts. All major manufacturing operations are highly automated and product exposure is nearly non-existent.	Excellent
8	**Plant Lighting and Protection** High intensity and fluorescent lighting is utilized throughout the plant.Adequate illumination is provided and lighting is protected from breakage that would create possible contamination. Light fixtures are maintained clean, free of cracks, dust or other materials that could cause contamination.	Acceptable
9	**Maintenance Standard (Support of GMPs, Housekeeping, Lubricants** There is a documented preventative maintenance program (Shawware Software) that covers the equipment and facilities. Permanent repairs are made promptly. Food-grade and non-food grade lubricants are well marked and not stored together.	Acceptable
Section notes:		

Section D Sanitation, Housekeeping and Hygiene

No	Question/Notes	Answer

Section D Sanitation, Housekeeping and Hygiene

No	Question/Notes	Answer
1	**Master Sanitation List and Monitoring** Periodic sanitation tasks are scheduled through the PM schedule or performed in response to the daily checklist. There is a documented cleaning procedure for operational areas, equipment, warehouse, storage, maintenance, locker rooms, cafeterias, break areas and toilet facilities with scheduled tasks that are monitored for completion and documented on a regular basis.	Acceptable
2	**Standard Sanitation Operating Procedures and Monitoring** Automated CIP systems are used for nearly all sanitation functions. There is a documented Standard Sanitation Operation Procedure that defines and specifies standard cleaning methods for equipment and facility structures. The procedure includes the frequency of cleaning, the chemicals used and the water temperatures where applicable. Records are kept of all deficiencies found and the corrective action that is taken to bring the equipment into a sanitary condition and prevent a re occurrence.	Acceptable
3	**Cleaning Chemical and Sanitizer Control** There are procedures that specify the proper dilution of chemicals and/ or sanitizers and all containers of cleaning chemicals and sanitizers are properly labeled. Chemical containers are used for their intended purpose only. Chemicals are securely stored during periods of non-use.	Acceptable
4	**Pre Op Monitoring and Corrective Action** A routine documented inspection program, conducted by the operator, is in place to assess sanitation practices and conditions prior to daily operation. Deficiencies are noted and corrective actions taken are documented. Micro swabs for environmental at specified locations are conducted on a frequency to cover all areas and lines of equipment; this provides a monthly turnaround in all locations.	Acceptable
5	**Verification of Cleaning Effectiveness** The effectiveness of the sanitation program is monitored visually prior to production and supplemented with an objective measurement at a frequency that demonstrates effectiveness. Results are documented.	Excellent
6	**Operational Housekeeping and Monitoring** All areas of the plant are kept exceptionally clean, orderly and free from accumulation of litter. Garbage, trash and waste materials are accumulated in identified containers and properly disposed of. No evidence of mold, mildew or slime on walls, floors, ceilings or equipment was observed. Floor drains are kept clean, odor free and covered. No tool storage or materials were observed on top of equipment, electrical boxes or window ledges.	Excellent
7	**Personal Hygiene and Good Manufacturing Practices** All employees wear clean company issued outer clothing, hair/ beard nets, eye protection, and foot protection. Employee training is provided that covers plant specific Good Manufacturing Practices, Personal Hygiene, Plant Sanitation, HACCP and Product Tampering Awareness. All sanitation employees receive training in basic food handling. Continuing refresher training is provided at least quarterly and records are kept of individual training programs and topics covered for each employee. Training is presented in an appropriate language to be clearly understood by all employees. Detailed dress codes and personal hygiene requirements are provided.	Acceptable
8	**RTE Sanitation and Corrective Action**	N/A
9	**GMP Self Inspections and Corrective Actions** Internal GMP self-inspections are conducted to verify compliance to policies and to evaluate the effectiveness of the policies. All aspects of sanitation and GMP compliance are included in the daily checklist used in each area. Follow-up audit activities are conducted to record the effectiveness of corrective actions for deficiencies and repeat items.	Acceptable
Section notes:		

Section E Rodent and Pest Control Management

No	Question/Notes	Answer
1	**Documented and Specific Pest Control Program** Pest control services are provided by "Ecolab Pest Elimination".There is a current pest management policy and program that outlines the responsibilities of the Pest Control Operator (PCO), the proper use of internal trapping devices, outside bait stations and the documentation of service and activity reports. Site maps for all traps and bait stations were current, Material Safety Data Sheet (MSDS) and the PCO applicator¿s license	Acceptable

Section E Rodent and Pest Control Management

No	Question/Notes	Answer
	and letter of insurance were current and on file.	
2	Outside Premises Management (Grounds, Waste Disposal Areas) There is a current pest management policy and program that outlines the responsibilities of the Pest Control Operator (PCO), the proper use of internal trapping devices, outside bait stations and the documentation of service and activity reports. Site maps for all traps and bait stations were current, Material Safety Data Sheet (MSDS) and the PCO applicator¿s license and letter of insurance were current and on file.	Acceptable
3	Inside Premises Management Interior conditions were orderly, clean , and in excelent repair throughout and allowed for easy access and evaluation along walls. Control measures are used at distances from food or food contact surfaces to avoid any potential for contamination. Trapping devices were in proper working condition and no bait stations were observed being used inside the plant or warehouse	Acceptable
4	Pest Tight Doors and Entrance Closures All doors are self closing, in good repair, maintained tight closing seals and no exterior holes/ cracks in walls, pipe chase, vent openings, windows, etc., provided easy access to pests.	Acceptable
5	Secure Storage and Documentation of Pest Related Chemicals Pest related chemicals for fogging are stored on site in a secured location with limited access. by the PCO. A detailed inventory log of chemicals received, quantities used, lot codes, the date used and for what purpose is maintained Containers are destroyed once empty. The inventory is evaluated regularly to verify that the quantities received, the amount used and the amount currently on hand balance. Safety precautions for storage of pest related chemicals are available. All other pest control chemicals are controlled by the PCO at an off site location.	Acceptable
6	Activity Reports Detailed with Corrective Actions The plant conducts quarterly review of the complete program for pest control in addition to a monthly walk through to verify current reports.Activity reports are available, indicating specific sites of activity, type of activity, recommended corrective action, specific chemicals used, quantities used, locations where used, the date used and for what purpose. Activity reports were signed by the PCO and by a designated plant representative. Deficiencies are addressed with corrective action documentation	Acceptable
Section notes:		

Section F Receiving and Inventory Control

No	Question/Notes	Answer
1	Incoming Vehicle Review and Documentation A written inspection program describes acceptable and/ or unacceptable conditions for all inbound carriers. All inbound carriers are inspected for food safety, quality and security related concerns at the time of receiving, by the dock receiving personnel. QA then approves the product (each lot) after sampling, and releasing after compliance to all safety, quality and physical specifications are verified.	Excellent
2	Specific Receiving Policies with Inspection and Acceptance Plans All ingredients and supplies are purchased from approved vendors. Current specifications for purchased ingredients and supplies were available. Incoming materials and ingredients are inspected for damage, contamination and other unacceptable conditions as described by the receiving policy. Records are maintained along with supplier codes for lot traceability.	Acceptable
3	Release Criteria for Ingredients A bar code system is used to control ingredients and materials in the system. All ingredients are maintained in a secure fashion and released for use against a defined approval program. An inventory management system is in place to assure proper rotation	Acceptable
4	Storage and Handling Policies and Practices Procedures for the storage and handling practices of ingredients and supplies have been established to assure they do not become a source of contamination. Receiving areas and storage locations are maintained in a clean and sanitary manner and ingredients and supplies are held under conditions necessary to maintain product integrity.	Excellent
5	Bulk Receiving Systems Sanitation and Monitoring Bulk ingredient handling and storage equipment is maintained in a sanitary and secure manner. Bulk	Acceptable

Section F Receiving and Inventory Control

No	Question/Notes	Answer
	Ingredients carriers are secured inside the building and all connection lines are maintained in a sanitary manner. Bulk milk products, and oil are received. Documented cleaning procedures and frequencies are established and followed	
6	**Restricted and/or Sensitive Ingredient Control, Including Chemical Compounds** Restricted ingredients, sensitive ingredients, allergenic materials and potentially toxic chemicals are stored separately and maintained under strict control. Toxic chemicals and flammable solvents are stored in secured and restricted areas. Usage records and inventories are maintained for toxic materials and Material Data Safety Sheet (MSDS) are readily available for all chemical compounds in the facility.	Acceptable

Section notes:

Section G Process and Product Evaluation

No	Question/Notes	Answer
1	**Process Control and Documentation Procedures** Process control systems are very well developed and documented. Most are highly automated.Process control procedures are established, monitored and documented to assure product is manufactured to meet all food safety requirements. In-process ingredients and products are adequately protected and properly labeled with date and lot number.	Excellent
2	**Specification and Formulation Control and Accuracy** All formulas are controlled at the division headquarters in Columbus, Ohio. Software is uploaded locally and access is very limited. All current specifications are controlled locally by QA. Records are available that demonstrate compliance to product formulations and finished product specifications. Test protocols and frequencies are followed as identified in the specification and production records are maintained for twelve months beyond product shelf life.	Excellent
3	**Routine Calibration of Operational Equipment and Measuring Devices (such as thermometers, scales, flow meters, counters, metal detectors, etc.)** Key process control devices are calibrated by an outside contractor at least annually and monitored internally on a regular basis to assure accuracy on a day-to-day basis. Thermometers used for product evaluations are calibrated on a daily basis, documented and traceable. All weighing scales are checked and documented daily to verify accuracy. Corrective actions when measuring devices are found to be out of calibration are documented.	Acceptable
4	**Foreign Material Control** Finished product is passed through a Rare Earth Magnet. There is a written procedure for the maintenance, set-up and verification testing of metal removal screens and magnets, documentation of set-up is part of the daily production records. The magnet includes removal of Stainless Steel at less than 2.5 mm. Screens applied to pipe lines at the liquid phase a particulate removal capabilities of less than 2.00 mm .	Acceptable
5	**Application of Statistical Control** Statistical control is used to determine the capability of the process equipment and the setting of critical limits for critical control points. Computer controlled systems automatically adjust for the system based on past performance. QA data is collected at multiple points for evaluation of line performance.	Acceptable
6	**Allergen and Sensitive Ingredient Controls** Production of products containing allergens is conducted under a detailed procedure to prevent the contamination of other products. Ingredients containing allergens are clearly identified as such and properly controlled in the production area. Labeling of products containing the presence of the allergens is conducted as required by regulations	Acceptable
7	**Documentation Showing Product Meets Specifications** Records are maintained to document that product is manufactured according to specification. Finished products are inspected and tested. Product is not shipped until all parameters meet specification and approved by management.	Acceptable
8	**Rework and Carryover Products** There is a documented procedure for managing rework and carry over products. Rework is traceable to its	Acceptable

Section G Process and Product Evaluation

No	Question/Notes	Answer
	original production and to finished product. Production dates and original lot numbers are carried forward in production documents. Rework and carry-over is kept to a minimum and used promptly at the first opportunity. There is a routine and documented "clean break" in the rework/ carryover cycle.	
9	Analytical Records Management Established systems ,data is stored in the LIMS system, (Lab Information Managements System), utilized to properly store and retrieve analytical information, documents, reports, records, etc All records are maintained for 4 years.	Acceptable
Section notes:		

Section H Packaging and Labeling

No	Question/Notes	Answer
1	Label Accuracy and Regulatory Compliance Labels received are checked for accuracy to mandatory requirements, color contrast and design as provided by the Divisional Label approval department. All labels are maintained in a secure location until the evaluations are completed. Obsolete/ irregular labels are well marked on Hold and held in a secure location waiting for proper destruction/ disposition. On-line scanners are used to read label bar codes and hourly verification of the scanners is conducted.	Excellent
2	Documented Net Weight or Count Compliance Policy and Performance A documented policy for net quantity compliance requires the calibration of quantity measuring devices. Calibration checks are conducted at the beginning and end of production and are documented on production records. All products are sold by net weight and line data is fed into a Stat Pack software program that feeds results to the computerized check weigher for automatic adjustments, when required.	Acceptable
3	Clear Manufacturing Codes on Individual and Cased Product Ink Jet codes consist of a 9 digit line (top) and a 7-digit line (bottom). Codes are read as follows: first line example–397927100: 39= month(consecutive count), 792=batch number, 71= product, 00=container size. Second line example–0700525: 070=Julian date, 0525= time. This code is also used on the case. A "use by" code is also embossed on the container end. All product coding is of such size, color and contrast to afford easy legibility at a reasonable distance. Each individual sell unit has a production or lot code. Packages within the sell unit have a lot code.	Acceptable
4	Package Integrity and Function for Distribution All packaging is designed and assembled to provide protection for the product from environmental and shipping conditions. Verification of proper sealing and closure of the packaging is conducted.Package codes are checked every 30 minutes.	Acceptable
5	Label Security and Obsolete Label Controls There is a written plan describing the security measures for labeling materials to prevent unauthorized or accidental use and to prevent the use of obsolete labels.	Acceptable
6	Tamper Evident Packaging No tamper evident statement is made on the units however, the composite cans have metal ends with a ezy open end that is tamper evident. Liquid bottle have caps that a seal must be broken in order to open the container. Tamper evident packaging is used and a monitoring program is in place and documented to insure that tamper evident features are effectively applied.	Acceptable
Section notes:		

Section I Storage and Shipping

No	Question/Notes	Answer
1	Warehouse and Finished Product Management Warehouse conditions are maintained and controlled in a manner to assure product integrity. All pallets of product are bar coded and orders specify the particular pallet to be used to fill the order (FIFO control).Finished product and packaging materials are held separated and away from chemicals. Product not "cleared" for shipment is clearly identified and stored in a location where it is not likely to be shipped in error.	Acceptable

Section I Storage and Shipping

No	Question/Notes	Answer
2	**Retained and Returned Products** Documented procedures requiring identification, secured segregation, documentation, evaluation, disposition and reconciliation of product that is placed on hold are established for non-conforming retained and returned products. Returned products are placed on hold immediately, designated areas are established for retained and returned products and an inventory log is maintained showing current product on hold and the disposition of all released product with proper authorization.	Acceptable
3	**Storage Facility and Dock Maintenance** Warehouse storage areas are clean and orderly and have adequate space around the periphery for access, inspection and cleaning. Items are stored off the floor, floors and walls are in good condition and emergency doors are tight fitting. Shipping docks, dock plates and levelers are clean and kept orderly.	Acceptable
4	**Transport Condition** Written procedures for acceptable carrier conditions are available to shipping personnel. Outbound trailers are inspected and results are documented. No product is loaded into unacceptable carriers. When non-dedicated carriers are used, trailer logs are assessed to determine if unacceptable materials had been present.	Acceptable
5	**Release Authorization to Ship Product** Release authorization is required before any product is shipped. Production items are assigned quarantined status in the inventory system. Following record review and product testing QA modifies the status in the system to release the products for shipment.	Acceptable
6	**Product Traceability** Procedures are established to effectively trace specific lots of ingredients, food contact packaging and finished products through the shipping and distribution channels. Traceability exercises are conducted at least twice per year to the first level of distribution. Management assessments of each traceability exercise are conducted and documented to provide a balance sheet of total quantity of product produced subject to the exercise vs. product shipped, product on hand and product otherwise documented (damaged, lost, samples, etc.), product unaccounted for, a calculated percent recovery and any corrective actions that are identified. The most recent traceability exercise demonstrated a 99.5% to 105% level of accountability within 4 hours.	Acceptable

Section notes:

Section J Analytical Records and Laboratory Support

No	Question/Notes	Answer
1	**Laboratory Facility and Staffing** A total of 42 lab employees, 24 in the chemistry lab, 9 in the micro lab, and 9 dedicated to incoming materials, control the evaluation of materials and final product conformance to required standards. Laboratories are adequately equipped and staffed to provide the essential technical support. Lab staff qualifications are documented, toxic supplies are securely stored and properly labeled and the laboratory is clean, orderly and well lit.	Excellent
2	**Laboratory Procedures and Documentation** Laboratory procedures are documented, authorized and date, by the Division headquarters.. Testing procedures are based on recognized and approved procedures and documentation of all testing is available	Excellent
3	**Laboratory Equipment Calibration** Records of laboratory balances and test equipment calibrated by a certifying company are documented. Calibrations checks conducted internally are documented with specific instrument identification, date of calibration and the individual performing the calibration check. They have internal company and external schools trained instrumentation personnel. They are required to have a degree in instrumentation.	Acceptable
4	**Analytical Accuracy Verification** Detailed test procedures with known test controls, work instructions, training records and record keeping are established to verify that monitoring and test results meet finished product specifications. Tests performed are documented and meet accepted standards of a recognized authority. Documented evidence is available that demonstrates laboratory test results are accurate and reliable.	Acceptable

Section notes:

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Section K Food Defense

No	Question/Notes	Answer
1	Management A Food Defense team has been established and a risk assessment has been conducted to evaluate intentional, internal and external vulnerabilities and risks that exist from ingredient sourcing, storage, processing, shipping of finished goods and personnel. A documented Food Defense program has been identified, organized, communicated and implemented and is fully understood by plant employees, suppliers and customers. Product and facility security roles and responsibilities are documented and defined and appropriate management controls have been initiated. The facility has a registration number from the applicable regulatory agency and unusual occurrences are documented and assessed by management	Excellent
2	Human Element All individuals entering the facility must show proof of identification, with their specific company ID badge. Temporary employees are fully supervised at all times. Contractors and visitors are required to show identification and sign in and out. Visitors are accompanied while in the facility and wear an ID badge supplied by the Company. A current roster of employees and work assignments is maintained and employees are prohibited from bringing personal items such as purses, cases, containers, lunch boxes, etc. into processing areas. A screening program is in place for all employees and a program to train Food Defense rules at the facility has been implemented. Training is documented for each individual at the facility.	Acceptable
3	Facility A schematic of the facility and outside grounds is available that identifies all entrances into the building, accesses to the roof and sensitive areas.. Cameras, lighting, fencing, and security service is very complete. Access to sensitive areas and utilities is restricted. When not in use, non-traffic doors, dock doors and utility access is secured. Emergency doors are alarmed. A process for issuing, tracking and retrieving keys, identification badges and passes for the buildings and for secure areas is documented.	Excellent
4	Operations The facility has been evaluated for vulnerability to sabotage and documented policies and procedures have been developed to address areas of concern. Non-employee drivers and delivery personnel have designated waiting areas. Trucks and/ or trailers are inspected before unloading. Damaged product, where the cause of damage is unknown, is not used. Transport vehicles are kept secure when not in the process of loading or unloading. Vehicles are secured after loading is completed and seal numbers are recorded.	Acceptable
Section notes:		

Section 3 Ingredients of Concern

No	Question/Notes	Answer
1	Does the plant use or store Peanuts or Peanut Products?	No
2	Does the plant use or store Tree Nuts?	No
3	Does the plant use or store Crustacea?	No
4	Does the plant use or store Fish?	No
5	Does the plant use or store Egg or Egg Products?	No
6	Does the plant use or store Milk or Milk Products?	Yes
7	Does the plant use or store Soybean or Soy Products?	Yes
8	Does the plant use or store Wheat, Corn (Maize) or Related Grains?	No
9	Does the plant use or store Mollusks?	No
10	Does the plant use or store Seeds?	No
11	Does the plant use or store Cottonseed Products?	No
12	Does the plant use or store Legumes?	Yes
13	Does the plant use or store Sulfites?	No
14	Does the plant use or store FD&C Yellow #5 or #6?	No
15	Does the plant use or store Monosodium Glutamate, Autolyzed yeast, Hydrolyzed	No

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Section 3 Ingredients of Concern

No	Question/Notes	Answer
	protein?	
16	Does the plant use or store Meat?	No
17	Does the plant use or store Poultry?	No
Section notes:		

Section 4 Foreign Material Control Information

No	Question/Notes	Answer
1	What is the Brand Sold to Costco?	Kirkland
2	What Product(s) are produced for Costco?	3/51.4 oz units/ case in Composite Can bodies with metal ends. The top metal end is Ezo open
3	Does plant pass individual sell units of finished product for Costco through a calibrated X-ray or metal detector? (Primals are considered finished products.) They utilize screens of 8-10 mesh and a Rare Earth magnet on the final dry powder just prior to filling into the container. Both screens and magnet are on a regular cleaning and examination schedule. Records are kept of the inspections.	No
4	Is the X-ray or metal detector calibration checked hourly?	No
5	If X-ray or metal detector calibrated with a ferrous test sample?	No
6	Enter ferrous test sample size used in mm.	N/A
7	If X-ray or metal detector calibrated with a non-ferrous test sample?	No
8	Enter non-ferrous test sample size used in mm.	N/A
9	If X-ray or metal detector calibrated with a stainless steel test sample?	No
10	Enter stainless steel test sample size used in mm.	N/A
Section notes:	When the product is in the liquid form it passes through 3 inline screens with sizes ranging from 8-10 mesh. The screens are checked at each shift period. The final dried product is passed over/ through a rotary Rare Earth Magnet that can attract Stainless Steel to particulate size of less than 2.5 mm.	

* Represents Non Compliances.

If you have any questions about this report, please contact your NSF Project Manager, JENNIFER FITZPATRICK at 734-827-6857 or fitzpatrick@nsf.org.